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K111753

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K111753.

807.92 (a)(1): Name: Hitachi Chemical Diagnostics
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Contact: Mr. Bunichiro Nakajima

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:

- Hitachi Clinical Analyzer S TEST Reagent Cartridge Cholesterol (CHO)
- Hitachi Clinical Analyzer S TEST Reagent Cartridge High Density Lipoprotein Cholesterol (HDL)
- Hitachi Clinical Analyzer S TEST Reagent Cartridge Low Density Lipoprotein Cholesterol (LDL)
- Hitachi Clinical Analyzer S TEST Reagent Cartridge Triglycerides (TG)

Common Name: Routine chemistry analyzer for lipid panel: total cholesterol (CHO), HDL, LDL, and triglycerides (TG)

Classifications: 21 CFR § 862.1175- Cholesterol (total) test system
21 CFR § 862.1475- Lipoprotein (HDL, LDL) test system
21 CFR § 862.1705- Triglyceride test system
All Class I Reserved, per 21 CFR 862.9(c)(4)

807.92 (a)(3): Identification of the legally marketed predicate devices

Instrument portion: Roche/Hitachi cobas 6000- K060373
Total cholesterol: Roche/Hitachi test reagent- K031824
HDL: Roche/Hitachi test reagent- K033610
LDL: Roche/Hitachi test reagent- K012287

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TG: Roche/Hitachi test reagent- K972250

Integrated system (instrument and lipid panel): Alfa Wasserman S40 system- K091413

807.92 (a)(4): Device Description

The Hitachi Clinical Analyzer is an automatic, bench-top, wet chemistry system intended for use in clinical laboratories or physician office laboratories. The instrument consists of a desktop analyzer unit, an operations screen that prompts the user for operation input and displays data, a printer, and a unit cover. The analyzer unit includes a single probe, an incubation rotor, carousels for sample cups and reagent cartridges, and a multi-wavelength photometer. The single-use reagent cartridges may be placed in any configuration on the carousel, allowing the user to develop any test panel where the reagent cartridges are available.

The S TEST reagent cartridges are made of plastic and include two small reservoirs capable of holding two separate reagents (R1 and R2), separated by a reaction cell/photometric cuvette. The cartridges also include a dot code label that contains all chemistry parameters, calibration factors, and other production-related information, e.g., expiration dating. The dimensions of the reagent cartridges are: 13.5 mm (W) × 28 mm (D) × 20.2 mm (H).

System operation: After the sample cup is placed into the carousel, the analyzer pipettes the sample, pipettes the reagent, and mixes (stirs) the sample and reagent together. After the sample and reagent react in the incubator bath, the analyzer measures the absorbance of the sample, and based on the absorbance of the reactions, it calculates the concentration of analyte in the sample. The test system can measure analytes in serum or heparin plasma and results are available in approximately 15 minutes per test. This submission is for the Lipid Panel, consisting of reagent cartridges for total cholesterol, HDL, LDL, and triglycerides.

Chemistry reactions:

Cholesterol

The cholesterol in the sample is cleaved into cholesterol esters and free cholesterol. The cholesterol esters become free cholesterol through the action of cholesterol esterase (CE). The free cholesterol is then oxidized by cholesterol oxidase (COD) to produce hydrogen peroxide, esters and free cholesterol. The cholesterol esters become free cholesterol through the action of cholesterol esterase (CE). The hydrogen peroxide oxidizes and condenses 4-aminoaminoantipyrine and N-ethyl-N-sulfobutyl-m-toluidine (ESBmT) under the influence of peroxidase (POD) to produce a reddish-purple pigment. Total cholesterol concentration is determined by measuring the absorbance of this reddish-purple pigment. The difference in absorbance, monitored bichromatically at 600 nm/800 nm, is directly proportional to the cholesterol concentration in the sample.

HDL

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By using a special surface-active agent that preferentially solubilizes HDL and not other lipoproteins (LDL, VLDL, and chylomicrons), the HDL cholesterol is measured via a quickly initiated enzymatic reaction. Therefore, only HDL cholesterol is specifically measured. The released hydrogen peroxide oxidizes and condenses 4-aminoaminoantipyrine and N,N'-bis(4-sulfobutyl)-m-toluidine disodium salt (DSBmT) in the presence of peroxidase (POD) to produce a reddish-purple pigment. HDL cholesterol concentration is determined by measuring the absorbance of this reddish-purple pigment. The difference in absorbance, monitored bichromatically at 600 nm/700 nm is directly proportional to the HDL concentration in the sample.

LDL

The method, using a combination of two surfactants, is based on the principle that each lipoprotein reacts with different surfactants, depending on their intrinsic physicochemical property. In the first reaction, Surfactant 1 changes the structure of only those lipoproteins other than LDL (i.e., chylomicron [CM], VLDL, and HDL), and the resulting micellar cholesterol is consumed by the cholesterol oxidase and the cholesterol esterase in a colorless reaction. In the second reaction, the remaining LDL is modified by Surfactant 2, and that form of cholesterol is measured in a color reaction.

TG

Free glycerol in the sample is converted to glycerol-3-phosphoric acid through the action of glycerol kinase (GK) and the adenosine triphosphate (ATP) substrate. Glycerol-3-phosphoric acid is converted to hydrogen peroxide via the action of glycerol-3-phosphate oxidase (GPO); peroxide is then decomposed into water and oxygen via the action of catalase. The neutral fat in the sample is quickly hydrolyzed into glycerol and fatty acid by the lipoprotein lipase (LPL) contained in the second reagent. The glycerol product is converted to glycerol-3-phosphoric acid via the action of GK and the ATP substrate, which in turn produces hydrogen peroxide via the action of GPO. The hydrogen peroxide oxidizes/condenses 4-aminoantipyrine and N-ethyl-N-sulfobutyl-m-toluidine (ESBmT), via the action of peroxidase (POD) to produce a reddish purple pigment. The original neutral fat concentration (triglyceride) is determined by measuring the absorbance of the reddish purple pigment produced. The difference in absorbance between the final reading and the blank, monitored bichromatically at 600 nm/800 nm, is directly proportional to the triglyceride concentration.

807.92 (a)(5): Intended Use

The Hitachi Clinical Analyzer with S TEST reagent cartridges for total cholesterol (CHO), HDL cholesterol (HDL), LDL cholesterol (LDL), and triglycerides (TG) is intended for the quantitative measurements of CHO, HDL, LDL, and TG in serum or heparinized plasma. The test system is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood, and lipid and lipoprotein metabolism disorders.

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- HDL measurements (lipoproteins) are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- LDL measurements (lipoproteins) are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

807.92 (a)(6): Technological Similarities and Differences to the Predicate
The following chart describes similarities and differences between the two test systems.

Characteristic	Hitachi S TEST Systems	PREDICATE(S)
Instrument Platform	Hitachi Clinical Analyzer	Roche cobas 6000 - K060373
		also, Alfa Wasserman S40- K091413
Cholesterol	K number- K111753	Roche K number- K031824
Device Class, Regulation Code	Class I (reserved), 21 CFR 862.1175	Same
Classification Product Code	CHH	Same
Intended Use	Quantitative determination of total cholesterol	Same
Testing Environment	Physician office (POL) or clinical lab	Clinical lab- cobas POL/Clin Lab - Alfa Wasserman
Test Principle	Enzymatic method (COD-POD method)	Enzymatic (cholesterol esterase and cholesterol oxidase)
Specimen Type	Serum and heparinized plasma	Same
Reportable Range	4 to 400 mg/dL	3.86 to 800 mg/dL
Detection Wavelength	600/800 nm	700/505 nm
Detection Limit	0.7 mg/dL	3.86 mg/dL
Linearity	1 to 435 mg/dL	3.86 to 800 mg/dL
Precision	%CVs range from 0.5% to 1.4% (POL testing)	%CVs range from 1.4% to 1.6% (from product labeling)
HDL	K number- K111753	Roche K number- K033610
Device Class, Regulation Code	Class I (reserved), 21 CFR 862.1475	Same
Classification Product Code	LBS	Same
Intended Use	Quantitative determination of HDL cholesterol	Same
Testing Environment	Physician office or clinical lab	Clinical lab- cobas POL/Clin Lab - Alfa Wasserman

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Test Principle	Enzymatic direct method	Enzymatic (cholesterol esterase and cholesterol oxidase) after removal of LDL and VLDL
Specimen Type	Serum and heparinized plasma	Same
Reportable Range	8 mg/dL to 150 mg/dL	3 to 121 mg/dL
Detection Wavelength	600/700 nm	700/600 nm
Detection Limit	0.6 mg/dL	3 mg/dL
Linearity	4 mg/dL to 485 mg/dL	3 to 121 mg/dL
Precision	%CVs range from 1.0% to 4.5% (from POL testing)	%CVs range from 0.9% to 1.5% (from product labeling)

Comparative chart- continued

Characteristic	**Hitachi S TEST Systems**	**PREDICATE(S)**
LDL	K number- K111753	Roche K number- K033610
Device Class, Regulation Code	Class I (reserved), 21 CFR 862.1475	Same
Classification Product Code	MRR	Same
Intended Use	Quantitative determination of LDL cholesterol	Same
Testing Environment	Physician office or clinical lab	Clinical lab- cobas POL/Clin Lab - Alfa Wasserman
Test Principle	Enzymatic direct method	Homogeneous enzymatic colorimetric
Specimen Type	Serum and heparinized plasma	Same
Reportable Range	8 to 400 mg/dL	3.86 to 548 mg/dL
Detection Wavelength	546/660 nm	700/600 nm
Detection Limit	0.8 mg/dL	3.86 mg/dL
Linearity	3 to 430 mg/dL	3.86 to 548 mg/dL
Precision	%CVs range from 1.3% to 2.0% (from POL testing)	%CVs range from 1.9% to 2.7% (from product labeling)
Triglycerides	K number- K111753	Roche K number- K972250
Device Class, Regulation Code	Class I (reserved), 21 CFR 862.1705	Same
Classification Product Code	CDT	Same
Intended Use	Quantitative determination of triglycerides	Same
Testing Environment	Physician office or clinical lab	Clinical lab- cobas POL/Clin Lab - Alfa Wasserman
Test Principle	Enzymatic method	Enzymatic and colorimetric

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Specimen Type	Serum and heparinized plasma	Same (plus EDTA plasma)
Reportable Range	7 mg/dL to 800 mg/dL	8.85 to 885 mg/dL
Detection Wavelength	570/700 nm	700/505 nm
Detection Limit	2.5 mg/dL	8.85 mg/dL
Linearity	2 to 848 mg/dL	8.85 to 885 mg/dL
Precision	%CVs range from 1.1% to 4.1% (from POL testing)	%CVs range from 1.6% to 2.0% (from product labeling)

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807.92 (b)(1): Brief Description of Nonclinical Data

A series of studies were performed that evaluated the following nonclinical performance characteristics for each analyte: analytical sensitivity (limits of detection), linearity, 20-day in-house precision, interference testing, in-house method comparisons, and matrices comparison between serum and heparin plasma.

Analytical Sensitivity (Limits of Detection)

The studies followed CLSI EP17-A for each analyte. The sensitivities were as follows:

CHO: 0.7 mg/dL
HDL: 0.6 mg/dL
LDL: 0.8 mg/dL
TG: 2.5 mg/dL

Linearity

The studies followed CLSI EP-6A for each analyte. The ranges of linearity were as follows:

CHO: 1 mg/dL to 435 mg/dL
HDL: 4 mg/dL to 485 mg/dL
LDL: 3 mg/dL to 430 mg/dL
TG: 2 mg/dL to 848 mg/dL

20-day In-house Precision

The studies followed CLSI EP5-A2, where three or four levels of samples were each tested four-times a day for 20 days. The results were as follows:

Precision Summary:

		Mean (mg/dL)	Within-Run %CV	Total %CV
Total Cholesterol	Level 1	116.5	0.9	1.7
n= 80 per level	Level 2	182.8	0.8	1.5
	Level 3	258.0	0.7	1.8
HDL	Level 1	35.3	3.0	3.8
n= 80 per level	Level 2	60.0	2.4	3.1
	Level 3	101.6	1.7	2.7
LDL	Level 1	37.7	1.4	5.2
n= 80 per level	Level 2	104.3	1.6	3.5
	Level 3	175.8	1.3	3.4
	Level 4	299.3	1.0	2.7
TG	Level 1	32.8	5.3	5.6
n= 80 per level	Level 2	129.7	2.0	2.6
	Level 3	366.5	1.3	2.5
	Level 4	620.1	1.4	2.4

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Interference Testing
The studies followed CLSI EP7-A2. The data demonstrated that none of the four analytes were affected by high levels of the following substances at the levels noted:

Hemoglobin: no interference up to 1000 mg/dL for CHO and LDL; 500 mg/dL for HDL and TG
Unconjugated bilirubin no interference up to 50 mg/dL for CHO, HDL, and TG; 25 mg/dL for LDL
Lipemia: no interference up to 2000 mg/dL for CHO; up to 725 mg/dL for HDL and up to 614 mg/dL for LDL (TG: N/A)
Ascorbic acid: no interference up to 50 mg/dL with any of the four test systems

Method Comparisons
The method comparison studies evaluated a minimum of 109 serum samples; matched aliquots were assayed with both the Hitachi Clinical Analyzer with S TEST reagent cartridges for CHO, HDL, LDL, and TG and the Roche/Hitachi cobas. The data were analyzed by least squares linear regression (Hitachi = y-axis), and the results were as follows:

Cholesterol (mg/dL)
n= 113
y = 0.98x + 2.2
correlation coefficient (r) = 0.996
95% confidence interval of the slope = 0.96 to 1.00
95% confidence interval of the y-intercept = -1.7 to 6.1

HDL (mg/dL)
n = 109
y = 0.99x +5.4
correlation coefficient (r) = 0.986
95% confidence interval of the slope = 0.96 to 1.03
95% confidence interval of the y-intercept = 3.6 to 7.3

LDL (mg/dL)
n = 122
y = 0.94x + 7.6
correlation coefficient (r) = 0.981
95% confidence interval of the slope = 0.90 to 0.97
95% confidence interval of the y-intercept = 3.0 to 12.1

TG (mg/dL)
n = 111
y = 1.04x +6.7
correlation coefficient (r) = 0.998
95% confidence interval of the slope = 1.03 to 1.05

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95% confidence interval of the y-intercept = 4.4 to 9.0

Matrices Comparisons
A study was performed to validate the use of heparinized plasma as well as serum for the Hitachi Clinical Analyzer with S TEST reagent cartridges for CHO, HDL, LDL, and TG. Approximately 40 matched serum/plasma samples that spanned the four dynamic ranges were assayed in singleton and the results were compared using least squares liner regression (plasma = y-axis). The performance characteristics were as follows.

Cholesterol (mg/dL)
y = 1.00x -3.0
correlation coefficient (r) = 0.999
95% confidence interval of the slope = 0.99 to 1.01
95% confidence interval of the y-intercept = -5.5 to -0.6

HDL (mg/dL)
y = 0.99x -2.2
correlation coefficient (r) = 0.999
95% confidence interval of the slope = 0.96 to 1.00
95% confidence interval of the y-intercept = -3.9 to -0.5

LDL (mg/dL)
y = 1.01x -3.9
correlation coefficient (r) = 0.999
95% confidence interval of the slope = 0.99 to 1.02
95% confidence interval of the y-intercept -6.4 to -2.3

TG (mg/dL)
y = 1.00x -1.3
correlation coefficient (r) = 0.999
95% confidence interval of the slope = 0.98 to 1.00
95% confidence interval of the y-intercept = -4.7 to 2.1

807.92 (b)(2): Brief Description of Clinical Data
Studies for precision and method comparisons (accuracy) were performed at three external POL-type sites to evaluate the Hitachi Clinical Analyzer with S TEST reagent cartridges for CHO, HDL, LDL, and TG in one of its targeted intended use environments, the physician's office laboratory.

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For the external site precision study, each site received three blinded serum samples (the Precision Panel, labeled A; B, and C) that were chosen to represent low, intermediate, and high concentrations of each analyte. Each sample was assayed six times per day for five days, reporting 30 results per level per analyte. Precision estimates for within-run precision and total precision were as follows:

Total Cholesterol (mg/dL)

n = 30 replicates per sample per site

Site	Sample	Mean	Within-run Precision		Total Precision	
			SD (mg/dL)	%CV	SD (mg/dL)	%CV
Site 1	A	121.3	0.8	0.6%	0.8	0.7%
Site 2	A	123.5	0.9	0.7%	1.2	1.0%
Site 3	A	123.5	1.2	1.0%	1.5	1.2%
Site 1	B	182.6	1.1	0.6%	1.3	0.7%
Site 2	B	185.0	1.1	0.6%	1.3	0.7%
Site 3	B	185.4	1.2	0.6%	1.3	0.7%
Site 1	C	242.3	0.9	0.4%	1.1	0.5%
Site 2	C	245.8	1.2	0.5%	1.4	0.6%
Site 3	C	247.1	1.8	0.7%	3.4	1.4%

HDL Cholesterol (mg/dL)

n = 30 replicates per sample per site

Site	Sample	Mean	Within-run Precision		Total Precision	
			SD (mg/dL)	%CV	SD (mg/dL)	%CV
Site 1	A	37.3	1.3	3.4%	1.7	4.5%
Site 2	A	36.3	0.6	1.6%	0.7	2.0%
Site 3	A	35.8	0.7	2.0%	1.3	3.7%
Site 1	B	67.1	0.5	0.8%	0.6	1.0%
Site 2	B	68.0	0.5	0.8%	1.1	1.6%
Site 3	B	64.6	0.7	1.0%	0.8	1.3%
Site 1	C	105.9	1.5	1.4%	2.0	1.9%
Site 2	C	106.3	1.1	1.0%	1.4	1.3%
Site 3	C	102.7	1.3	1.3%	1.6	1.6%

LDL Cholesterol (mg/dL)

n = 30 replicates per sample per site

Site	Sample	Mean	Within-run Precision		Total Precision	
			SD (mg/dL)	%CV	SD (mg/dL)	%CV

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Site 1	A	41.0	0.6	1.5%	0.7	1.7%
Site 2	A	42.5	0.8	1.9%	0.8	1.8%
Site 3	A	41.3	0.8	2.0%	0.8	2.0%
Site 1	B	108.9	1.3	1.2%	1.4	1.3%
Site 2	B	112.3	1.5	1.4%	1.7	1.5%
Site 3	B	109.1	2.3	2.1%	2.2	2.0%
Site 1	C	183.5	2.6	1.4%	3.1	1.7%
Site 2	C	191.3	2.4	1.2%	3.5	1.8%
Site 3	C	181.2	2.6	1.4%	3.1	1.7%

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Triglycerides (mg/dL)
n = 30 replicates per sample per site

Site	Sample	Mean	Within-run Precision		Total Precision	
			SD (mg/dL)	%CV	SD (mg/dL)	%CV
Site 1	A	32.1	0.8	2.6%	1.1	3.4%
Site 2	A	33.6	1.1	3.3%	1.1	3.3%
Site 3	A	31.4	1.2	4.0%	1.3	4.1%
Site 1	B	115.0	3.0	2.6%	3.5	3.0%
Site 2	B	120.2	1.4	1.2%	1.5	1.3%
Site 3	B	115.4	2.2	1.9%	2.8	2.4%
Site 1	C	291.0	1.9	0.7%	3.4	1.2%
Site 2	C	301.5	3.7	1.2%	3.5	1.2%
Site 3	C	289.1	2.5	0.9%	3.3	1.1%

For the external site method comparisons study, each POL site received approximately 50 blinded serum samples that were chosen to represent as full a range of analyte concentrations as possible, and a central laboratory received a matched aliquot for each serum sample. Each sample was assayed by the Hitachi system at the POL sites, and by the Roche cobas 6000 (predicate system) at the central laboratory. The results were analyzed by least squares linear regression (Hitachi = y-axis), and the performance characteristics were as follows:

POL ACCURACY DATA SUMMARY- Total Cholesterol mg/dL

Site #	n	Range	Regression Equation	"r"	Standard Error	CI* Slope	CI Intercept
1	52	60 to 329	y = 0.97x +2.5	0.99	3.45	0.95 to 0.98	-1.1 to 6.1
2	50	60 to 334	y = 0.98x +4.1	0.99	4.92	0.95 to 1.00	-1.0 to 9.3
3	51	60 to 333	y = 1.00x +0.7	0.97	13.54	0.94 to 1.08	-13.7 to 15.2

*95% Confidence Interval

POL ACCURACY DATA SUMMARY- HDL mg/dL

Site #	n	Range	Regression Equation	"r"	Standard Error	CI Slope	CI Intercept
1	52	15 to 111	y = 0.96x +7.6	0.98	4.22	0.91 to 1.00	4.9 to 10.3
2	50	16 to 114	y = 0.97x +7.9	0.98	3.90	0.91 to 1.03	4.8 to 11.0
3	51	14 to 115	y = 0.93x +7.8	0.99	3.67	0.89 to 0.98	5.3 to 10.3

POL ACCURACY DATA SUMMARY- LDL mg/dL

Site #	n	Range	Regression Equation	"r"	Standard Error	CI Slope	CI Intercept
1	52	26 to 274	y = 0.94x +3.8	0.99	8.08	0.90 to 0.99	-1.7 to 9.4
2	50	26 to 283	y = 0.95x +3.6	0.98	9.42	0.89 to 1.01	-3.5 to 10.8
3	51	25 to 276	y = 0.93x +6.4	0.98	8.04	0.89 to 0.98	0.6 to 12.3

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POL ACCURACY DATA SUMMARY- TG mg/dL

Site #	n	Range	Regression Equation	"r"	Standard Error	CI Slope	CI Intercept
1	52	36 to 619	y = 1.05x+4.9	0.99	6.95	1.04 to 1.07	1.4 to 8.4
2	52	21 to 712	y = 0.94x + 3.3	0.99	8.06	0.93 to 0.96	0.1 to 6.5
3	51	35 to 605	y = 1.07x -6.5	0.99	7.78	1.05 to 1.10	-10.1 to -2.9

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Hitachi Clinical Analyzer with reagent cartridges for CHO, HDL, LDL, and TG. The test system was shown to be safe and effective for its intended use.

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Public Health Service

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c/o Erika B Ammirati, RAC, MT (ASCP)
Consultant
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DEC 14 2011

Re: k111753
Trade/Device Name: Hitachi Clinical Analyzer S TEST Reagent Cartridges- Cholesterol (CHO), HDL Cholesterol (HDL), LDL Cholesterol (LDL), And Triglycerides (TG)
Regulation Number: 21 CFR 862.1705
Regulation Name: Triglyceride test system.
Regulatory Class: I, meets limitations of exemption 862.9 (c) (4)
Product Code: CDT, CHH, LBS, MRR, JJE
Dated: December 9, 2011
Received: December 12, 2011

Dear Ms. Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if Known): K111753

Device Name:

Hitachi Clinical Analyzer S TEST Reagent Cartridges- Cholesterol (CHO), HDL cholesterol (HDL), LDL cholesterol (LDL), and triglycerides (TG)

Indications for Use:
The Hitachi Clinical Analyzer with S TEST reagent cartridges for total cholesterol (CHO), HDL cholesterol (HDL), LDL cholesterol (LDL), and triglycerides (TG) is intended for the quantitative measurements of CHO, HDL, LDL, and TG in serum or heparinized plasma. The test system is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood, and lipid and lipoprotein metabolism disorders.
- HDL measurements (lipoproteins) are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- LDL measurements (lipoproteins) are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111753